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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/327,750	06/07/1999	TAKA-AKI SATO	59131/JPW/AK	5864

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/16/2003

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/327,750

Applicant(s)

SATO, TAKA-AKI

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 134-146 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 134, 135, 137-142 and 144-146 is/are rejected.
- 7) ☒ Claim(s) 136 and 143 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. Amendment H, filed 7/28/03, has been entered into the record.
- B. Claims 134-146 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Title

- A. The objection to the title has been withdrawn in view of Applicants' amendment to more clearly state the claimed subject matter.

3. Abstract

- A. The objection to the abstract has been overcome in view of Applicants' submission of a new, shorter abstract which does not contain legal phraseology. However, the abstract is 151 words, which exceeds the 150 word limit. Therefore, if this case becomes allowable, the abstract may need to be shortened.

4. Specification

- A. The objection to the specification is withdrawn since Applicants have clarified the NADE protein used in the examples is the mouse NADE of SEQ ID NO:13.

5. Claim Rejections - 35 USC § 101

- A. The rejection of claims 134-146 under 35 USC 101 has been withdrawn in view of Applicants' clarification of Bunone et al. regarding the relationship between "p75" and "TrKa" as well as for their clarification that NF-kB suppression by NADE alone could not induce apoptosis.

6. Claim Rejections - 35 USC § 112, first paragraph - enablement

- A. The rejection of claims 134-146 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments that the present invention possesses utility as discussed above.

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B. Claims 134, 135, 137-142 and 144-146 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 4/23/03. Applicants argue that the claims are now drawn to NADE proteins, as opposed to all cell death executors. Applicants argue that the term "NADE" represents a group of proteins capable of binding the p75 receptor to regulate apoptosis and that the specification discloses an example of the NADE of SEQ ID NO:12. However, Applicants argue that they also disclose NADE proteins of SEQ ID NO:30-39.

These arguments have been considered, but are not deemed persuasive. First, Applicants are enabled for the claimed methods using the NADE proteins of SEQ ID NO:13. Therefore, claims 136 and 143 are enabled. However, Applicants have not shown that the proteins of SEQ ID NO:30-39 are, in fact, NADE members. However, Figure 1H only discloses that the proteins of SEQ ID NO:30-39 are homologous to the NADE of SEQ ID NO:13. Homology, alone, is insufficient to demonstrate that the proteins of SEQ ID NO:30-39 are NADE proteins. Applicants have not provided any working examples of the function of SEQ ID NO:30-39, including that of binding the p75 receptor to regulate apoptosis. Applicants have only provided guidance and working examples of the protein of SEQ ID NO:13. Therefore, it would not be predictable to the artisan which proteins would be able to bind p75 and regulate apoptosis.

Therefore, due to the guidance and working example only of the NADE of SEQ ID NO:13 in its ability to bind p75 and regulate apoptosis, it would not be predictable to the artisan what other proteins would be able to perform the same function. Given this, the breadth of the claims is excessive with regard to Applicants claiming all NADE proteins able to bind p75 and regulate apoptosis. Therefore, the Examiner maintains that undue experimentation is required to practice the invention as claimed. If Applicants were able to demonstrate that the proteins of SEQ ID NO:30-39 were, in fact, NADE proteins, then the enablement of the claims may be reconsidered.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 134, 135, 137-142 and 144-146 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 5-6 of the Office Action dated 4/23/03. Applicants argue that the NADE genus was disclosed in the specification as originally filed, adequately describing the NADE features and providing numerous embodiments of its species. Applicants argue that pages 16 and 57 of the specification describe the characteristics of the NADE genus. This description discloses that the NADE proteins are hydrophilic and acidic and possess a p75 binding site, a leucine-rich NES and ubiquitination sequences. Applicants argue that they also disclose NADE proteins of SEQ ID NO:30-39.

These arguments have been considered, but are not deemed persuasive. First, Applicants have adequately described methods using the NADE proteins of SEQ ID NO:13. Therefore, claims 136 and 143 are not part of this rejection. However, Applicants have not shown that the proteins of SEQ ID NO:30-39 are, in fact, NADE members. However, Figure 1H only discloses that the proteins of SEQ ID NO:30-39 are homologous to the NADE of SEQ ID NO:13. Homology, alone, is insufficient to demonstrate that the proteins of SEQ ID NO:30-39 are NADE proteins. Therefore, Applicants have not adequately described any NADE proteins other than that of SEQ ID NO:13 and the human NADE. Therefore, only two embodiments of the species have been described, but the human counterpart is characterized as a NADE protein based solely on homology to the mouse NADE of SEQ ID NO:13. The fact that the proteins are hydrophilic, acidic, possess a NES and ubiquitination sequences is not sufficient to adequately describe the genus of NADE proteins, since these characteristics are not specific to NADE proteins. The most specific characteristic is that these proteins possess a p75 binding site. However, p75 may have more than one function and therefore would be expected to bind to proteins other than NADE. Therefore, the argument that the proteins possess a p75 binding site in the absence of any other supporting evidence, other than the general teachings that the proteins are hydrophilic, acidic and possess a NES and ubiquitination sequences, is insufficient to show that Applicants were in possession of the claimed genus at the time of the invention.

8. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. The specification remains rejected to under 35 USC 112, first paragraph, as containing new matter. The Examiner acknowledges the receipt of the Sequence Listing submitted 11/27/02. However, there is no statement over the attorney's signature that the newly submitted sequence listing and CRF are identical and contain no new matter. This statement by the attorney will overcome this rejection.

9. Claim Rejections - 35 USC § 112, second paragraph

A. Claims 134, 135, 137-142 and 144-146 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on pages 6-7 of the Office Action dated 4/23/03. Applicants argue that the metes and bounds of the NADE genus was disclosed in the specification, specifically on pages 16 and 57. This description discloses that the NADE proteins are hydrophilic and acidic and possess a p75 binding site, a leucine-rich NES and ubiquitination sequences.

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This argument has been considered, but is not deemed persuasive. The fact that the proteins are hydrophilic, acidic, possess a NES and ubiquitination sequences is not sufficient to define the metes and bounds of the genus of NADE proteins, since these characteristics are not specific to NADE proteins. The most specific characteristic is that these proteins possess a p75 binding site. However, p75 may have more than one function and therefore would be expected to bind to proteins other than NADE. Therefore, the argument that the proteins possess a p75 binding site in the absence of any other supporting evidence, other than the general teachings that the proteins are hydrophilic, acidic and possess a NES and ubiquitination sequences, is insufficient to clearly define the term "NADE."

10. Conclusion

A. No claim is allowable. Claims 136 and 143 are objected to since they depend from rejected base claims. However, these claims would be allowable if rewritten in independent format and included all the limitations of the base claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

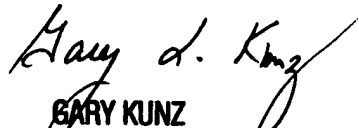
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 09, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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